With respect to the Declaration, it is noted for the examiner's convenience that:

a) The Corcoran Declaration is document C2 listed in the PTO 1449 considered by the examiner on June 10, 2005. This document is referred to as OD11 in the European Opposition documents being submitted herewith.

b) OD29 is document C5 listed in the PTO 1449 being filed herewith.
In this document, it may be noted that the sensitivity of detection of impurities in its Fig 2 chromatagram appears clearly to be set many times lower than that of the new material in Figure 1.

The examiner's comments in the first two complete paragraphs on page 3 of the office action emphasize the nonobvious nature of the invention. As noted, drug makers will always try to provide the highest purity product reasonably achievable. In any event, FDA will certainly require drug manufacturers to do so. Thus, it is clear that motivation has existed for many years to enhance the purity of fludarabine phosphate over that previously commercially accepted by FDA for administration to humans. As noted on page 2 of the previously submitted Tilstam declaration, FDA had approved a fludarabine phosphate product having a purity of 97.67%. As the examiner has implied, and as noted by Tilstam, why would FDA permit such a relatively high level of impurities to be contained in a commercial drug product if it were routine to increase the purity? Clearly, such could not have been routine or both the drug manufacturer and, especially, FDA would have required higher purity.

In the last paragraph on page 3 of the office action, the examiner states that, "When claiming a purer form of a known compound, it must be demonstrated that the purified material possess [sic] properties and utilities not possessed by the unpurified material." Whatever the correctness this principle of law might have had in the legal decisions cited by the examiner, it is not true that this is the only basis on which a purer form of a known compound can be patented.

As previously discussed, when a claimed product was not enabled by the prior art before filing of a patent application and when the patent application for the first time enabled such a product, then the product is for the first time patentable. The fact that the product is a purer form of a prior art product does not change the applicability of this principle, especially under the circumstances here where the product is an FDA approved drug for which there existed a high

motivation as pointed out by the examiner with respect to increases in its purity.

Accordingly, the claims have been shown to be patentable.

A new copy of item C13 mentioned in the PTO form 1449 of June 10, 2005 is provided in essence. It contained the Test Report discussed in the accompanying declaration. Additional copies of DE 19543052 and its translation are filed also. See B1 of the same 1449 form. Also filed are papers from the opposition proceeding and appeal in the corresponding EPO patent, which subject to the appeal, currently stands revoked.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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